Remarks/Arguments:

With the present amendment, claims 16-18, 20-39, and 42-45 are pending.

Claim rejections

Claim rejections under 35 U.S.C. §103

Claims 16, 20-26 and 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,967,744 to Chua ("Chua") in view of U.S. Patent No. 5,890,490 to Aylsworth et al. ("Aylsworth") and U.S. Patent No. 4,249,527 to Ko et al. ("Ko"). Applicants respectfully traverse this rejection.

Independent claim 16 recites, inter alia, a system for delivering humidified gas to a patient. The system comprises a supply unit configured to deliver humidified gas and a delivery tube assembly having a delivery tube with a proximal end and a distal end. The delivery tube assembly also has a fitting positioned at the proximal end of the delivery tube and releasably coupled to said supply unit. The delivery tube assembly is configured to transfer heat to the humidified gas received from said supply unit. A nasal cannula is releasably coupled to the distal end of the delivery tube to receive humidified gas from the delivery tube of the delivery tube assembly.

Independent claim 32 recites, *inter alia*, a method for delivering humidified gas to a patient. The method comprises the steps of releasably connecting a fitting of a proximal end of a delivery tube to a supply unit; releasably coupling a nasal cannula to a distal end of the delivery tube; and delivering humidified gas from the supply unit, through the delivery tube, and into the nasal cannula for delivery to the patient.

Chua discloses a breathing circuit that includes a patient connector 50 that is inserted into a patient's mouth for the patient to inhale the breathing gas generated by Chua's device. Co-axial tube 30 is used to provide an inspiratory supply line 40 that provides breathing gas from a ventilator 5 to a mouthpiece 54 and an expiratory tube 32 that allows expired air to be exhausted from the patient and to an exit connector 66 and back to the ventilator 5 through a return line 12. Additionally, Chua's operation requires the use of the expiratory tube 32. As the patient exhales, the patient "must exhale air out the expiratory tubing 32." Col. 4, lines 18-19. Emphasis added.

Aylsworth discloses a gas flow system that includes a nasal cannula 11 that is connected to an outlet port 9. Aylsworth also discloses that the nasal cannula 11 may include other patient connected devices, such as an oxygen mask. (*See* column 3, lines 61-65). Aylsworth also discloses a tube 31 that is coupled to a tee 29. (See column 4, lines 9-11). Aylsworth fails to disclose or suggest that the nasal cannula 11 is coupled to a breathing circuit.

Ko discloses a continuous positive airway pressure administration apparatus 20 that includes an adapter 144, a connector 146, and a nasal cannula 148. (*See* column 7, lines 65-66; Fig. 1).

In the Office Action, it was alleged that the difference between Chua and claim 16 was a nasal cannula releasably coupled to the distal end of the delivery tube to receive humidified gas from the delivery tube of the delivery tube assembly. The Office Action further alleged that it would have been obvious to modify the respiratory mouthpiece or the like of Chua to substitute a mask and nasal cannula because it would have provided the advantages of ensuring a secure and covered patient connection via a mask and providing humidified gas directly to a patient's respiratory passages via a nasal cannula as taught by Aylsworth. It was further stated that, to the extent, if any, that the nasal cannula of Aylsworth may not be releasably coupled, resort is had to Ko, which is said to teach releasably coupling a nasal cannula or an endotracheal tube to a connector member of a gas delivery tube for the purpose of providing a means for releasably connecting a plurality of different patient interfaces to a gas delivery conduit. The Office Action further concluded that it would have been obvious to releasably couple a nasal cannula to the distal end of the gas supply tube of Chua because it would have provided a means for releasably connecting a plurality of different patient interfaces to a gas delivery conduit as taught by Ko.

Further, it was stated in the Office Action that claim 32 is substantially equivalent in scope to claim 16 and is included in Chua as modified by Aylsworth and Ko for the reasons set forth above with respect to claim 16.

Applicants base their traverse of this rejection on numerous grounds. Applicants respectfully submit that there is no suggestion to modify the references to arrive at the claimed invention. Also, Applicants submit that the proposed combination would be inoperative. Additionally, Applicants respectfully submit that the proposed combination frustrates the purpose of the primary reference. Further, Applicants respectfully submit that the Examiner

has not provided any convincing reasoning why it would be obvious to combine the prior art as suggested.

Unsuggested modification

In *Ex parte Metcalf,* 67 U.S.P.Q.2d 1633 (May 2, 2003), the U.S. PTO Board of Patent Appeals and Interferences stressed that there must be objective motivation to support an obviousness rejection. More specifically, the mere fact that teachings found in the prior art could be combined as proposed by an Examiner does not make the combination obvious "absent some teaching, suggestion or incentive supporting the combination." *Id.* at 1635 (citing *Carella v. Starlight Archery and Pro Line Co.*, 231 USPQ 644, 647 (Fed. Cir. 1986)). There is no suggestion in Chua to modify Chua to add a nasal cannula. Chua uses co-axial tube 30 to provide an inspiratory tube 40 and an expiratory tube 32 that are both connected to a patient connector 50 as part of a breathing circuit. As shown in Fig. 2, patient connector 50 is inserted in the patient's mouth. The expiratory tube 32 is critical to Chua's invention because it is used to transport expiratory gases away from the patient. Chua's breathing circuit requires an expiratory line to complete the circuit. The nasal cannula of the present invention is not suitable or intended for use in a breathing circuit because there is no return for expiratory gases. Also, nowhere does Chua suggest modifying his breathing device with any type of different end device to supply breathing gas to the patient. Further, nowhere does Chua suggest that the patient connector 50 is releasably connected to the co-axial tube 30. Therefore, Applicants respectfully submit that there is no suggestion in Chua to modify his invention to include the claimed nasal cannula that is releasably coupled to the delivery tube.

Further, none of the remaining cited art suggests substituting its preferred apparatus of delivering breathing gas with a nasal cannula. If anything, Ko suggests substituting an endotracheal tube for a nasal cannula (Col 10, lines 29-31). As for his nasal cannula, Ko only states that a nasal cannula 148 is provided at a lower end of a vertical arm. *See* Col. 7, lines 66-67. As for his endotracheal tube, Ko teaches only to substitute the endotracheal tube (not shown) for the nasal cannula. Nowhere does Ko teach or suggest that either his cannula or endotracheal tube are releasably coupled to a delivery tube, as is recited in the present claims. Aylsworth discloses connecting his nasal cannula 11 to an outlet port 9. Aylsworth also suggests including an oxygen mask with his nasal cannula (Col. 3, lines 63-65). Aylsworth fails to disclose, however, how an oxygen mask is included with a nasal cannula.

Further, neither Aylsworth nor Ko disclose or suggest using their devices as part of a breathing circuit, such as Chua's. Aylsworth and Ko each fail to disclose how to connect their respective end devices (Aylsworth's cannula/mask and Ko's cannula/endotracheal tube) to an expiratory line in a breathing circuit.

Inoperative combination

Chua discloses co-axial tube 30 to provide an inspiratory tube 40 and an expiratory tube 32 that are both connected to breathing connector 50 as part of a breathing circuit. Assuming, *arguendo*, that one were to attempt to substitute Chua's breathing connector 50 with a nasal cannula, there is no way to connect the nasal cannula so that expired gases pass from the nasal cannula through the expiratory tube 32. Therefore, Applicants respectfully submit that the suggestion to modify Chua with the nasal cannula and mask of Aylsworth, as suggested by the Examiner, would render Chua inoperative. Further, neither Chua nor Aylsworth disclose or suggest how any connection between a nasal cannula/mask combination would be made with the breathing connector 50. Therefore, even if the separate components *could* be combined as suggested in the Office Action, there is no support in either reference that teaches *how* such a combination would be physically made.

Frustration of Purpose

Applicants respectfully submit that the proposed combination of Chua with Aylsworth to substitute Chua's respiratory mouthpiece with a nasal cannula of Aylsworth would frustrate the purpose of Chua's breathing *circuit*. Chua's device is designed so that "the patient must exhale air out of expiratory tubing 32." Col. 4, lines 18-19. The proposed substitution of Chua's mouthpiece with Aylsworth's nasal cannula frustrates the purpose of Chua's breathing circuit, because the proposed nasal cannula does not support expiration into Chua's expiratory tube 32. Therefore, the proposed combination is improper.

No convincing reasoning

In the Office Action, it is stated that "[i]t would have been obvious to releasably couple a nasal cannula to the distal end of the gas supply tube of Chua because it would have provided a means for releasably connecting a plurality of different patient interfaces to a gas delivery conduit as taught by Ko." Office Action, page 3. Especially in view of the fact that Chua relates to a breathing circuit and that a nasal cannula would render the circuit inoperative, the Office Action has failed to present a convincing line of reasoning as to why the claimed subject matter

as a whole, including its differences over the prior art, would have been obvious. In particular, the Office Action fails to state a reason as to why one would *want* to couple a nasal cannula to Chua's supply line. Such modification would render the expiratory portion of Chua's device inoperative, defeating the purpose of Chua's invention.

For at least the reasons cited above, Applicants respectfully submit that independent claims 16 and 32 are patentable over the proposed combination of Chua with Aylsworth and Ko. Applicants respectfully request reconsideration and allowance of claims 16 and 32.

Claims 20-26 all depend, either directly or indirectly, from claim 16, and Applicants respectfully submit that claims 20-26 are patentable over the cited prior art for at least the same reasons as set forth above with respect to claim 16.

Claims 17, 18, and 27-30 stand rejected under 35 U.S.C. §103(a) as unpatentable over Chua in view of Aylsworth and Ko, and further in view of U.S. Patent No. 5,349,946 to McComb ("McComb"). McComb is cited for an alleged flow rate of between 2 to 150 liters per minute. Claims 17, 18, 28, and 29 all ultimately depend from claim 16, and Applicants respectfully submit that McComb fails to cure the deficiencies of the cited prior art with respect to claim 16. Claims 17, 18, and 27-29 are all therefore patentable over the proposed combination of Chua with Aylsworth, Ko, and McComb for at least the reasons as set forth above with respect to claim 16. Reconsideration and allowance of claims 17, 18, and 27-29 is respectfully requested.

The Office Action states that claim 30 is substantially equivalent in scope to claim 17 and is included in Chua as modified by McComb for the reasons set forth with respect to claim 17. Claim 30 has been amended to recite, *inter alia*, humidified gas being delivered at a relative humidity in the range of about 95 % to about 100%. McComb, on the other hand, recites the delivery of breathing gas at approximately 92.5% relative humidity at a continuous flow rate of 35 liters per minute. Col. 5, line 68 - Col. 6, line 1, which is below the claimed range of between about 95% and about 100%. Chua fails to disclose or suggest a relative humidity of delivered breathing gas.

Because the proposed combination of Chua and McComb fails to teach or suggest the claimed limitation of delivering breathing gas at a relative humidity in the range of about 95 % to about 100%, Applicants respectfully submit that the rejection of claim 30 is improper. Reconsideration and allowance of claim 30 is respectfully requested.

Claims 31 and 33 stand rejected under 35 U.S.C. §103(a) as unpatentable over Chua in view of McComb and Aylsworth. Claim 31 has been amended to recite, *inter alia*, delivering

humidified air at a relative humidity in the range of about 95 % to about 100%. Claim 33 has been amended to recite, *inter alia*, delivering a humidified gas at a relative humidity in the range of about 95 % to about 100%. McComb and Chua are discussed above with respect to claim 30. Aylsworth fails to disclose a percentage of relative humidity in the gas that is delivered to a patient.

Because the proposed combination of Chua with McComb and Aylsworth fails to teach or suggest the claimed limitation of delivering humidified air or humidified gas at a relative humidity in the range of about 95 % to about 100%, Applicants respectfully submit that the rejection of each of claims 31 and 33 is improper. Reconsideration and allowance of claims 31 and 33 is respectfully requested.

Claim rejections under 35 U.S.C. §102

Claims 34-45 stand rejected under 35 U.S.C. §102(b) as anticipated by PCT Publication WO 86/02276 to Blackmer et al. ("Blackmer"). Claims 40 and 41 have been canceled, rendering the rejection of these claims moot.

Amended claim 34 recites, *inter alia*, a system for delivering humidified gas to a patient. The system comprises a supply unit configured to deliver breathing gas and a delivery tube releasably coupled to the supply unit. The delivery tube is configured to transfer heat to the breathing gas received from the supply unit. The breathing gas is humidified by fluid that has flowed through and *reverses direction in the delivery tube*.

In order to anticipate a claim under 35 U.S.C. §102, the reference must teach every element of the claim. M.P.E.P. §2131. Furthermore, "the identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) and M.P.E.P. §2131.

Blackmer discloses an embodiment in FIG. 9 that provides liquid to humidify a breathing gas in a humidifier 2. Prior to entering the humidifier, the liquid flows through delivery tube 26 from the discharge end proximate to cannula 51 toward the humidifier. As shown by the dashed liquid flow arrows of FIG. 9, Blackmer fails to disclose or suggest the liquid flowing through and reversing direction within the delivery tube, as is recited in claim 34.

Because Blackmer fails to disclose or suggest all of the limitations of claim 34, Applicants respectfully submit that the rejection of amended claim 34 is improper. Reconsideration and allowance of amended claim 34 is respectfully requested. Claims 35-38 all ultimately depend

from claim 34, and Applicants respectfully submit that claims 35-38 are all patentable over the cited prior art for at least the same reasons as set forth above with respect to claim 34. Reconsideration and allowance of claims 35-38 is respectfully requested.

Claim 39 recites, *inter alia*, a warming and humidifying system for a breathing gas comprising a fluid supply, a means for heating the breathing gas with fluid from the fluid supply, and a means for humidifying the breathing gas with the fluid after the fluid has heated the breathing gas.

Claim 39 includes "means for" language that must be interpreted under 35 U.SC. §112, sixth paragraph. Therefore, claim 39 "shall be construed to cover the corresponding structure . . . described in the specification and equivalents thereof." 35 U.S.C. §112, sixth paragraph. "[T]he PTO may not disregard the structure disclosed in the specification corresponding to such language when rendering a patentability determination." *In re Donaldson Co.*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994).

The specification discloses "means for heating the breathing gas with fluid from the fluid supply" as a delivery tube that provides for flow of liquid through the delivery tube in a first direction that reverses flow direction to a second direction proximate to the cannula. The liquid heats the breathing gas as the liquid travels in both directions through the delivery tube.

Blackmer fails to disclose or suggest a delivery tube that provides for flow of liquid through the delivery tube in a first direction that reverses flow direction to a second direction proximate to the cannula such that the liquid heats the breathing gas as the liquid travels in both the first and second directions through the delivery tube. Because Blackmer fails to disclose or suggest all of the limitations of claim 39, Applicants respectfully submit that the rejection of claim 39 is improper. Reconsideration and allowance of claim 39 is respectfully requested.

Claim 42 recites, *inter alia*, a method of delivering a breathing gas to a patient, the method comprising the steps of: coupling a delivery tube to a supply unit; coupling a nasal cannula to the delivery tube; delivering breathing gas from the supply unit to the delivery tube such that the breathing gas flows in a first direction through the delivery tube; *heating the breathing gas with a fluid in the delivery tube such that the fluid flows in at least the first direction through the delivery tube;* and delivering the breathing gas from the delivery tube to the nasal cannula for delivery to the patient.

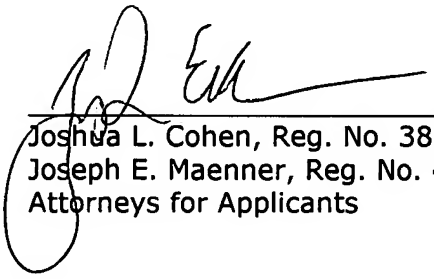
Blackmer, FIG. 9, discloses breathing gas flowing through delivery tube 26 in a first direction, and liquid heating the breathing gas that flows in a *second* direction, counter to the first direction. Blackmer fails to disclose or suggest heating the breathing gas with a fluid in the delivery tube such that the fluid flows *in at least the first direction through the delivery tube*, as is recited in claim 42.

Because Blackmer fails to disclose or suggest all of the limitations of claim 42, Applicants respectfully submit that the rejection of claim 42 is improper. Reconsideration and allowance of claim 42 is respectfully requested. Claims 43-45 all ultimately depend from claim 42, and Applicants respectfully submit that claims 43-45 are all patentable over the cited prior art for at least the same reasons as set forth above with respect to claim 42. Reconsideration and allowance of claims 43-45 is respectfully requested.

Conclusion

In light of the above amendments and arguments, Applicants respectfully submit that claims 16-18, 20-39, and 42-45 are in condition for allowance. Prompt reconsideration and allowance is respectfully requested.

Respectfully submitted,



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